Gambro
10810 West Collins Avenue
Lakewood, CO 80215

NOV - 2 2007

5.0 510(K) SUMMARY

Submitter's Name	Gambro
Address	10810 West Collins Avenue Lakewood, CO 80215
Establishment Registration Number	2087532
Date of Summary	March 7th, 2007
Telephone Number **Fax Number**	(303) 231-4094 (303) 542-5138
Contact Person	Thomas B. Dowell, Regulatory Affairs Project Manager
Name of the Device	Phoenix®Hemodialysis Delivery System 3.35 Catalogue Number: 6023006700
Common or Usual Name	Hemodialysis Delivery System
Classification Name	Classification Name: High Permeability Hemodialysis System Device Class: II Product Code: 78KDI Regulation Number: 876.5860
Indications for Use	The Phoenix® Hemodialysis delivery system is intended to be used to provide high flux and low flux hemodialysis, hemofiltration and ultrafiltration on patients weighing 15 Kilograms or more. The Phoenix system is to be used with either high or low permeability dialyzers. The device is intended to be used by trained operators when prescribed by a physician, in a chronic care dialysis facility or acute care unit.
Identification of the Legally Marketed Device (Predicate Device)	Phoenix®Hemodialysis Delivery System 3.00 Catalogue Number: 6023006700 Classification Name: High Permeability Hemodialysis System Device Class: II Product Code: 78KDI Regulation Number: 876.5860

Gambro
10810 West Collins Avenue
Lakewood, CO 80215

510(k) SUMMARY, continued

Device Description

Phoenix® is a self-contained, microprocessor-controlled device that provides hemodialysis and ultrafiltration-only therapies. The system consists of the Hemodialysis Machine in use with a blood tubing set designed for the machine, a dialyzer, a heparin-filled syringe, a BiCart® column (sodium bicarbonate powder), and other appropriate dialysate concentrates. The machine has many built-in features which are intended to enhance the ease of providing patient dialysis treatments. Phoenix® has a modular structure.

Device Comparison Table

	Predicate Phoenix® Hemodialysis Delivery System Version 3.00	**Modified Device** Phoenix® Hemodialysis Delivery System Version 3.35
Indication for Use	The Phoenix® Hemodialysis Delivery System is indicated for patients in acute or chronic renal failure and when the physician prescribes hemodialysis or ultrafiltration. The Phoenix® Hemodialysis Delivery System may be used with both high permeability and low permeability (conventional) dialyzers.	The Phoenix® Hemodialysis delivery system is intended to be used to provide high flux and low flux hemodialysis, hemofiltration and ultrafiltration on patients weighing 15 Kilograms or more. The Phoenix system is to be used with either high or low permeability dialyzers. The device is intended to be used by trained operators when prescribed by a physician, in a chronic care dialysis facility or acute care unit.
Dedicated Disposable Sets	Gambro Cartridge® Blood Set	Gambro Cartridge® Blood Set
Anticoagulation	Heparin Syringe Pump 0.5 – 10 ml/hr Accuracy: ± 5% or ± 0.2 ml/h	Heparin Syringe Pump 0/0.5 – 10 ml/hr Accuracy: ± 5% or ± 0.2 ml/h

Gambro
10810 West Collins Avenue
Lakewood, CO 80215

	Predicate Phoenix® Hemodialysis Delivery System Version 3.00	**Modified Device** Phoenix® Hemodialysis Delivery System Version 3.35
Blood Flow Rate	10 – 500 ml/min Accuracy: ± 10%	10 – 580 ml/min Accuracy ± 10% if pressure before the pump is not lower (more negative) than – 150 mmHg
Fluid Removal Rate from Patient	0 – 4 Kg/h Accuracy: ±2.5 % of actual value or ±50 ml/h, whichever is greater	0 – 4 Kg/h Dialysate flow rate at 350 ml/min: Accuracy (on total Weight removed): ±(2% UF rate + 35 g/hr) Dialysate flow rate at 500 ml/min: Accuracy (on total Weight removed): ±(2% UF rate + 50 g/hr) Dialysate flow rate at 800 ml/min: Accuracy (on total Weight removed): ±(2% UF rate + 80 g/hr)
Dialysate Flow Rate	350 – 1000 ml/min Accuracy: ± 5%	350 – 800 ml/min Accuracy: ± 5%
Transmembrane Pressure	-200 to +500 mmHg	-100 to +450 mmHg
Ultrafiltration Rate	0 – 4 Kg/h Accuracy: ±2.5 % of actual value or ±50 ml/h, whichever is greater	0 – 4 Kg/h Accuracy: ±2 % of actual value.
Dialysate Temperature	34 – 40 °C	34 – 39.5 °C
Dialysate Conductivity	13-17 mS/cm	13-17 mS/cm
Arterial and Venous Pressure	Arterial: -400 to +150 mmHg Venous: 100 to +450 mmHg	Arterial: -400 to +150 mmHg Venous: 0 to +450 mmHg

K070647
PAGE 4 OF 4

510(k) SUMMARY, continued

Description and Conclusion of Testing

Nonclinical Testing:
The nonclinical testing performed for the Phoenix® System 3.35 included component level hardware testing, testing required to support the declarations of conformity to standards contained in this 510(k) submission, testing required by process to ensure compliance with other international standards applicable to hemodialysis machines as well the static and dynamic software testing, e.g. unit testing, code inspections, testing targeted to the changes implemented in software version 3.35, regression testing, human factors evaluations and testing that was performed by internal and external independent personnel with the appropriate skills.

Conclusion:
The successful non-clinical testing demonstrates the safety and effectiveness of the Phoenix®Hemodialysis Delivery System when used for the defined indications for use and demonstrates that the device for which the 510(k) is submitted performs as well as or better than the legally marketed predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 2 2007

Mr. Thomas B. Dowell
Regulatory Affairs Project Manager
Gambro
14143 Denver West Parkway
LAKEWOOD CO 80401

Re: K070643
Trade/Device Name: Phoenix® Hemodialysis Delivery System 3.35
Regulation Number: 21 CFR §876.5860
Regulation Name: High permeability hemodialysis system
Regulatory Class: II
Product Code: KDI
Dated: October 25, 2007
Received: October 26, 2007

Dear Mr. Dowell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K070643

Gambro
10810 West Collins Avenue
Lakewood, CO 80215

Traditional 510(k)
Phoenix® System 3.35

Indications for Use

510(k) Number (if known): _____

Device Name: Phoenix® Hemodialysis Delivery System 3.35

Indications for Use:

The Phoenix® Hemodialysis delivery system is intended to be used to provide high flux and low flux hemodialysis, hemofiltration and ultrafiltration on patients weighing 15 Kilograms or more. The Phoenix system is to be used with either high or low permeability dialyzers. The device is intended to be used by trained operators when prescribed by a physician, in a chronic care dialysis facility or acute care unit.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K070643